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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/712,364	11/14/2000	Louis G. Lange III	93,473-G	5701
27716	7590	12/03/2004	EXAMINER	
CV THERAPEUTICS, INC. 3172 PORTER DRIVE PALO ALTO, CA 94304			MAIER, LEIGH C	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/712,364

Applicant(s)

LANGE ET AL.

Examiner

Leigh C. Maier

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 13, 2004 has been entered.

Claims 12 and 17 have been amended. Claims 12-17 are pending. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Any objection or rejection not expressly repeated has been withdrawn.

Claim Rejections - 35 USC § 103

Claims 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over LANGE et al (WO 90/12579).

The invention has been amended to recite a limitation with respect to the method of preparing the sulfated polysaccharide (SPS) to be used in the therapeutic method.

Applicant's arguments filed September 13, 2004 have been fully considered but they are not completely persuasive. Applicant points out that "[t]he inventiveness of the recited method is further evidenced by the fact that method of treatment claims that recited the administration of high molecular weight sulfated polysaccharide made using the recited method were found patentable in the parent application, U. S. Patent No. 6,632,801."

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The examiner has reviewed the decision rendered by the Board of Patent Appeals and Interferences (*Ex parte* Louis B. Lange, III *et al.*) in said parent application. It is noted that the decision turns on the lack of motivation to select a particular molecular weight cutoff—in this case, 75 kD. The Board looked at the product, *per se*, but was silent regarding the method of preparing it. The examiner adopts this position for the purposes of the instant prosecution.

The product of the instant invention differ from the parent product in that the limitations allow for more than five times the amount of SPS having molecular weight of less than 75 kD, and there is no indication that the products used in LANGE have a wt% of SPS of greater than 5%. The products are prepared comprising a method of sulfating the polysaccharides at temperatures ranging from 0°C to room temperature, typically 20-22°C. It is noted that the instant specification exemplifies the sulfation of cellulose at temperatures of 20°C and 22°C, resulting in products having wt% of 2.5 and 4.0, respectively, of these low molecular weight products. See Table VI. Therefore, as the Board has noted, there is no teaching that would lead one of ordinary skill to prepare a product in such a way to ensure a wt% of less than 0.98% (the limitation in the parent), it appears likely that the products used in LANGE would meet the broader limitation in the instant claims.

Since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

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As discussed in the previous Office action, LANGE teaches the administration of SPSs, such as high molecular weight cellulose sulfate, which act as inhibitors of human cholesterol esterase, to lower serum cholesterol. See abstract, page 5, and example 4. The reference is silent regarding the presence of residual inorganic sulfates in the products or the removal thereof. However, the examples exemplify the purification of the products by methods such as dialysis and recrystallization, which would be expected to remove or reduce inorganic impurities.

The reference further suggests the use of said polysaccharides in combination with other agents having cholesterol-lowering activity. Particular agents suggested by the reference are ACAT inhibitors (see page 14, lines 19-25) and lovastatin (see page 15, lines 21-24), but the use of the polysaccharides in combination with other agents is not specifically exemplified.

As noted above, it appears likely that the LANGE products would meet the limitation regarding the amount of SPS having molecular weight of less than 75 kD.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have administered the disclosed SPSs taught by LANGE, in combination with other agents, such as ACAT inhibitors or lovastatin. The ordinarily skilled practitioner would have been motivated to obtain the combined effect of the agents in lowering serum cholesterol with a reasonable expectation of success, as LANGE had taught this method. It would have been further obvious to purify the SPSs taught in the reference to remove residual non-therapeutic reactants. The reference specifically exemplifies the purification of the SPSs, and one of ordinary skill would recognize the desirability of removing inorganic sulfates for an agent meant for pharmaceutical use in humans.

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Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Wednesday, or Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (571) 272-0661, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 872-9306.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.



Leigh C. Maier
Patent Examiner
November 23, 2004